# In the United States Court of Federal Claims

#### **OFFICE OF SPECIAL MASTERS**

SHANNON FROGGE, \*

\* No. 16-1693V

Petitioner, \* Special Master Christian J. Moran

\*

V.

\*

SECRETARY OF HEALTH \* Filed: March 31, 2020

AND HUMAN SERVICES, \*

\* Fact ruling; onset

Respondent. \*

Amy A. Senerth, Muller Brazil, LLP, Dresher, PA, for petitioner; Lisa A. Watts, United States Dep't of Justice, Washington, DC, for respondent.

## UNPUBLISHED RULING FINDING FACTS\*

Shannon Frogge filed a petition for compensation under the National Childhood Vaccine Injury Compensation Program, 42 U.S.C. § 300aa–10 through 34 (2012), alleging that she suffers from Guillain-Barré syndrome ("GBS"), paresthesias, and neuropathy as a result of the influenza vaccine she received on December 23, 2013. Pet., filed Dec. 23, 2016, at 1. The parties dispute when she started to experience various symptoms after the vaccination. For the reasons explained below, the undersigned finds that a preponderance of the evidence supports an onset date of February 1, 2014, for a resumption of Ms. Frogge's right upper quadrant symptoms and an onset date of May 15, 2014, for Ms. Frogge's twitching.

<sup>\*</sup> The E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002), requires that the Court post this decision on its website. Anyone will be able to access this decision via the internet (<a href="https://www.uscfc.uscourts.gov/aggregator/sources/7">https://www.uscfc.uscourts.gov/aggregator/sources/7</a>). Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

### **Procedural History**

As support for her claim and the onset of her injury, Ms. Frogge filed affidavits and medical records. The Secretary filed a Rule 4(c) report that disputed Ms. Frogge's claim and the onset of her injury. In particular, the Secretary points to the lack of support for Ms. Frogge's alleged onset of symptoms in the contemporaneously created medical records.

When special masters are confronted with discrepancies between medical records and affidavits, special masters are encouraged to hold hearings to evaluate the testimony of the affiants. See Campbell v. Sec'y of Health & Human Servs., 69 Fed. Cl. 775, 779-80 (2006). The undersigned ordered the parties to file a joint statement of issues identifying factual disputes that would be resolved after testimony. Order, issued Aug. 22, 2018. On August 30, 2018, the parties filed a joint statement of issues.

A fact hearing was held on October 11, 2018, during which Ms. Frogge testified in person. Also testifying for the petitioner were Ms. Frogge's primary care physician, Dr. Tayler; close friend, Amy Hunt; and sister, Jaime Wagner. After the hearing, Ms. Frogge submitted additional exhibits, including outstanding medical records.

The parties were then ordered to file briefs on onset addressing each of the issues identified in the joint statement. Order, issued Jan. 4, 2019. Ms. Frogge filed her brief on April 15, 2019, and respondent filed his brief on May 3, 2019. Upon further review, Ms. Frogge was ordered to file missing medical records. Order, issued Sept. 6, 2019. Since the missing medical records and related documents have now been filed, this matter is ripe for adjudication.

# **Standard for Finding Facts**

Petitioners are required to establish their cases by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [one] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

The process for finding facts in the Vaccine Program begins with analyzing the medical records, which are required to be filed with the petition. 42 U.S.C. § 300aa–11(c)(2). Medical records that are created contemporaneously with the events they describe are presumed to be accurate. <u>Cucuras v. Sec'y of Health & Human Servs.</u>, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Not only are medical records presumed to be accurate, they are also presumed to be complete, in the sense that the medical records present all the patient's medical issues. Completeness is presumed due to a series of propositions. First, when people are ill, they see a medical professional. Second, when ill people see a doctor, they report all their problems to the doctor. Third, having heard about the symptoms, the doctor records what he or she was told.

Appellate authorities have accepted the reasoning supporting a presumption that medical records created contemporaneously with the events being described are accurate and complete. A notable example is <u>Cucuras</u>, in which petitioners asserted that their daughter Nicole began having seizures within one day of receiving a vaccination, although medical records created around that time suggested that the seizures began at least one week after the vaccination. <u>Cucuras</u>, 993 F.2d at 1527. A judge reviewing the special master's decision stated that "[i]n light of [the parents'] concern for Nicole's treatment . . . it strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred." <u>Cucuras v. Sec'y of Health & Human Servs.</u>, 26 Cl. Ct. 537, 543 (1992), <u>aff'd</u>, 993 F.2d 1525 (Fed. Cir. 1993).

Decisions by judges of the Court of Federal Claims have followed <u>Cucuras</u> in affirming findings by special masters that the lack of contemporaneously created medical records can contradict a testimonial assertion that symptoms appeared on a certain date. <u>See, e.g., Doe/70 v. Sec'y of Health & Human Servs.</u>, 95 Fed. Cl. 598, 608 (2010) (stating "[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), <u>aff'd sub nom. Rickett v. Sec'y of Health & Human Servs.</u>, 468 Fed. Appx. 952 (Fed. Cir. 2011) (non-precedential opinion); <u>Doe/17 v. Sec'y of Health & Human Servs.</u>, 84 Fed. Cl. 691, 711 (2008); <u>Ryman v. Sec'y of Health & Human Servs.</u>, 65 Fed. Cl. 35, 41-42 (2005); <u>Snyder v. Sec'y of Health & Human Servs.</u>, 36 Fed. Cl. 461, 465 (1996) (stating "The special master apparently reasoned that,

if Frank suffered such [developmental] losses immediately following the vaccination, it was more likely than not that this traumatic event, or his parents' mention of it, would have been noted by at least one of the medical record professionals who evaluated Frank during his life to date. Finding Frank's medical history silent on his loss of developmental milestones, the special master questioned petitioner's memory of the events, not her sincerity."), aff'd, 117 F.3d 545, 547-48 (Fed. Cir. 1997).

The presumption that contemporaneously created medical records are accurate and complete is rebuttable, however. For cases alleging a condition found in the Vaccine Injury Table, special masters may find when a first symptom appeared, despite the lack of a notation in a contemporaneous medical record. 42 U.S.C. § 300aa–13(b)(2). By extension, special masters may engage in similar fact-finding for cases alleging an off-Table injury. In such cases, special masters are expected to consider whether medical records are accurate and complete. To overcome the presumption that written records are accurate, testimony is required to be "consistent, clear, cogent, and compelling." Blutstein v. Sec'y of Health & Human Servs., No. 90-2808V, 1998 WL 408611, at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998).

In determining the accuracy and completeness of medical records, special masters will consider various explanations for inconsistencies between contemporaneously created medical records and later given testimony. The Court of Federal Claims has identified four such explanations for explaining inconsistencies: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. La Londe v. Sec'y Health & Human Servs., 110 Fed. Cl. 184, 203 (2013), aff'd, 746 F.3d 1334 (Fed. Cir. 2014).

In weighing divergent pieces of evidence, special masters usually find contemporaneously written medical records to be more significant than oral testimony. <u>Cucuras</u>, 993 F.2d at 1528. Testimony offered after the events in question is less reliable than contemporaneous reports when the motivation for accurate explication of symptoms is more immediate. <u>Reusser v. Sec'y of Health & Human Servs.</u>, 28 Fed. Cl. 516, 523 (1993). However, compelling oral testimony may be more persuasive than written records. <u>Campbell</u>, 69 Fed. Cl. at 779 ("[L]ike any norm based upon common sense and experience, this rule should

not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); Camery v. Sec'y of Health & Human Servs., 42 Fed. Cl. 381, 391 (1998) (this rule "should not be applied inflexibly, because medical records may be incomplete or inaccurate"); Murphy v. Sec'y of Health & Human Servs., 23 Cl. Ct. 726, 733 (1991) ("[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance") (citation omitted), aff'd, 968 F.2d 1226 (Fed. Cir. 1992).

The relative strength or weakness of the testimony of a fact witness affects whether this testimony is more probative than medical records. An assessment of a fact witness's credibility may involve consideration of the person's demeanor while testifying. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley v. Sec'y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

#### **Analysis of Issues set out in the Joint Statement of Issues**

The undersigned will address the issues that the parties presented in the joint statement.

1. Does a preponderance of the evidence support a finding that petitioner suffered an adverse reaction to a flu vaccine administered on November 16, 2012?

The parties do not dispute that Ms. Frogge received a flu vaccination on November 16, 2012, at Dr. Tayler's office. Exhibit 27 at 36. On December 14, 2012, she returned to Dr. Tayler's office and was seen by Steven Webster, a physician's assistant, complaining of cough, sinus pain, sore throat, and runny nose for the past two weeks. <u>Id.</u> at 32. Ms. Frogge was diagnosed with acute sinusitis and prescribed a Z-Pak and Singular. <u>Id.</u> at 33. Based on these prescriptions, it appears that the physician's assistant suspected an infection or allergies as the cause of Ms. Frogge's symptoms. Tr. 23 (Dr. Tayler confirming intended use of Singular for allergies).

On December 31, 2012, Ms. Frogge came back to Dr. Tayler complaining of headaches, fever, body aches, and cough. <u>Id.</u> at 30. Dr. Tayler noted that the Z-Pak had not appeared to help Ms. Frogge and that he now suspected that she had influenza. <u>Id.</u> at 30-31. He did not administer an influenza test but instructed her to return if her symptoms worsened. <u>Id.</u> Ms. Frogge had a return visit on January

3, 2013, now complaining of rash, fever, headache, and fatigue. <u>Id.</u> at 28. She tested negative for influenza. <u>Id.</u> at 28. Dr. Tayler diagnosed her with an allergic reaction and noted that he now believed her other symptoms to be a "significant viral infection." <u>Id.</u> at 29; Tr. 26-30. Her symptoms resolved soon after that. Tr. 188.

<u>Note</u>: The undersigned understands that the parties agree that Ms. Frogge suffered problems such as cough, sinus pain, sore throat, and runny nose that are reflected in medical records created in December 2012 and January 2013. Given this agreement, the undersigned understands that the parties are seeking an additional finding regarding the etiology of these problems.

In the joint statement, the parties presented this issue as whether a factual finding could be made of Ms. Frogge's adverse reaction to the November 12, 2012 flu vaccination. A finding of an adverse reaction is tantamount to a finding of causation and causation is a topic on which experts typically opine. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994). After a hearing to determine when events in Ms. Frogge's life happened but before the parties have had an opportunity to obtain reports from experts, the undersigned declines to find whether the headaches, fever, body aches, cough, rash, or fatigue described above were a reaction to the November 12, 2012 flu vaccination. The undersigned notes that evidence is in conflict. Compare Tr. 29-30, 72-73 (Dr. Tayler's testimony) with exhibit 12 at 14 (Dr. Watkins's records).

- 2. If the answer to #1 is yes, then:
  - a. What symptoms constituted the adverse reaction?
  - b. When did they occur?

As noted above, the undersigned has declined to make a finding whether Ms. Frogge suffered an adverse reaction to the November 12, 2012 flu vaccination. Since these questions presume an affirmative finding of an adverse reaction, they cannot be answered at this time.

- 3. Does a preponderance of the evidence support a finding that petitioner had a history of any of the following symptoms prior to the December 23, 2013 vaccination:
  - a. right upper quadrant pain?
  - b. right-sided lower chest wall pain?; or
  - c. right upper abdominal pain?
  - If so, which symptoms preceded vaccination?

The parties agree that Ms. Frogge had a history of right quadrant pain, right-sided lower chest wall pain, and right upper abdominal pain prior to the December 23, 2013 vaccination. Pet'r's Br., filed Apr. 15, 2019, at 2-3; Resp't's Br., filed May 3, 2019, at 2. Although Ms. Frogge has been treated for these types of pain, the medical records and testimony indicated that Ms. Frogge had not complained about these types of pain in the months leading up to the December 23, 2013 vaccination. Exhibit 12 at 25; Tr. 20-21 (Dr. Tayler's description of Ms. Frogge as "one of the more healthy patients"), 190 (Ms. Frogge's describing herself as "happy and healthy"). The undersigned finds that the record supports the parties' agreement about Ms. Frogge's pre-vaccination history of pain.

- 4. Does a preponderance of the evidence support a finding that petitioner had any of the following symptoms on December 23, 2013:
  - a. right upper quadrant pain?
  - b. right-sided lower chest wall pain?; or
  - c. right upper abdominal pain?

If so, which symptoms were present on the date of vaccination?

The parties agree that Ms. Frogge was not experiencing these symptoms on December 23, 2013. Pet'r's Br. at 3-4; Resp't's Br. at 2-3. As noted above, the undersigned finds that the record supports the parties' agreement that Ms. Frogge was not experiencing these types of pain on December 23, 2013.

5. Does a preponderance of the evidence support a finding that petitioner suffered an adverse reaction to the December 23, 2013, flu vaccine?

It is undisputed that Ms. Frogge received a flu vaccination on December 23, 2013 at Dr. Tayler's office. Exhibit 27 at 27. At that appointment, Ms. Frogge complained of constipation, cold intolerance, and generalized fatigue. <u>Id.</u> at 25. Per Ms. Frogge's request, Dr. Tayler ordered thyroid function tests and administered an influenza vaccine. <u>Id.</u> at 25, 27. Two weeks later, Ms. Frogge testified that she began to feel the same way she had felt after her 2012 flu vaccination, body aches and other symptoms but no rashes. Tr. 190-91. She testified to feeling extremely unwell for about four or five days. <u>Id.</u> On January 8, 2014, she called Dr. Tayler to inform him that she was feeling unwell and that she had been exposed to the flu, but she did not make an appointment to see him. Exhibit 1 at 173. She attempted to manage her symptoms by taking ibuprofen and other over-the-counter medications. Tr. 192.

Ms. Frogge's next visit to Dr. Tayler was on February 6, 2014, where she presented with right upper quadrant pain. Exhibit 27 at 23. At the appointment, Ms. Frogge described the pain as "more bothersome the past several weeks to several months." Id. At the hearing, she characterized the pain as "more like a deep ache-type rather than a stabbing pain like I'd experienced a long time ago [before her nerve block injection]." Tr. 194. The medical records from the visit and subsequent testing state that Ms. Frogge denied having headaches, fever, fatigue, abdominal pain, right lower quadrant pain, right lower flank pain, leg pain, or arm pain. Exhibit 47 at 43, 45; exhibit 27 at 23. Dr. Tayler ordered an ultrasound of her abdomen and a lipase test. Id. at 24; exhibit 47 at 36-37, 46; exhibit 50 at 10-11.

At this time, Ms. Frogge's cousin, Tom Freeman, was visiting Ms. Frogge and her family in Utah. Exhibit 45 (flight itinerary) at 1. Tom Freeman is a physician who has clinical experience with athletes. Exhibit 44 at 1. Dr. Freeman noticed that Ms. Frogge appeared to be in general pain, "moving slowly with guarded motion." <u>Id.</u> at 2. Dr. Freeman accompanied Ms. Frogge to the hospital for her testing and when he left on February 9, 2014, she was still experiencing abdominal pain, fatigue, and malaise. <u>Id.</u> at 2. The undersigned finds Dr. Freeman's written testimony to be persuasive. Ms. Frogge was not well at this time.<sup>3</sup>

On April 23, 2014, Ms. Frogge visited Dr. Tayler again complaining of "off and on" right upper quadrant pain. Exhibit 27 at 20. Ms. Frogge reported that the right upper quadrant pain had been "going on for many years" but has become "more frequent and bothersome." <u>Id.</u> At the hearing, while Ms. Frogge generally remembered her symptoms getting worse since February 2014, she couldn't "remember, like, what exactly came on as it came on, but I just continually had neurological-type things and muscle things happening through that time." Tr. 196.

<sup>&</sup>lt;sup>1</sup> Ms. Frogge's recently submitted medical records and insurance records (exhibits 48-51) helped to fill out the picture of the medical treatment around this time.

<sup>&</sup>lt;sup>2</sup> The brief "Chief Complaint" section of this February 6, 2014 visit summarizes Ms. Frogge's condition as "RUQ [right upper quadrant] pain x 6 weeks, loose stool today, no appetite." Exhibit 27 at 23.

<sup>&</sup>lt;sup>3</sup> Ms. Hunt's testimony was generally not persuasive. At the hearing, Ms. Hunt testified that she observed Ms. Frogge having neurological symptoms, such as twitching, during her January-February 2014 visit. This timing of neurological symptoms is contradicted by the medical records that only document flu-like symptoms and regional pain during that time.

Since he was unable to determine the etiology, Dr. Tayler ordered extensive blood tests and noted that he would speak to a radiologist to determine whether a thoracic spine MRI would assist in diagnosing Ms. Frogge. Exhibit 27 at 22.

When Ms. Frogge returned to Dr. Tayler on May 30, 2014, she reported a twitching sensation in her right upper quadrant where she had been experiencing pain. Exhibit 27 at 16. While she was experiencing shortness of breath, she reported to Dr. Tayler that she could "exercise just fine." <u>Id.</u> Her test results had returned normal, and Dr. Tayler referred her to a pulmonologist and neurologist. <u>Id.</u> at 19. Soon after, at a June 2, 2014 appointment, Ms. Frogge saw Dr. Tayler for a severe back spasm, but he noted "no weakness, numbness, and tingling in the extremities." <u>Id.</u> at 14. Ms. Frogge testified that the twitching began in her abdomen and then proceeded to her legs. Tr. 194. At a June 5, 2014 chiropractic appointment, Ms. Frogge complained of twitching in her stomach and fingers. Exhibit 10 at 2.

For the same reasons that the undersigned declined to find an adverse reaction to the November 12, 2012 vaccination, a finding of an adverse reaction to the December 23, 2013 vaccination will not be reached at this point.

- 6. If the answer to #5 is yes, then:
  - a. What symptoms constituted the adverse reaction?
  - b. When did they occur?

While the undersigned has declined to answer question #5 at this time, the type and timing of Ms. Frogge's symptoms can be addressed. Ms. Frogge has alleged an adverse reaction of GBS and her neurologic symptoms, such as twitching, relate most directly to GBS. At the April 23, 2014 appointment, Ms. Frogge did not complain of twitching and, at the May 30, 2014 appointment, Ms. Frogge complained of twitching in her right upper quadrant. By June 5, 2014, Ms. Frogge's twitching was now in her stomach and fingers. Given Ms. Frogge's documented history of seeking medical attention relatively close in time to the presentation of her symptoms, the undersigned finds that Ms. Frogge's twitching began on May 15, 2014.

7. Does a preponderance of the evidence support a finding that Petitioner developed the onset of new neurologic symptoms within one year of the December 23, 2013, flu vaccine?

Yes, as explained in response to question # 6, the undersigned finds that Ms. Frogge's twitching began on May 15, 2014.

- 8. *If the answer to #7 is yes, then:* 
  - a) What new neurologic symptoms did she develop?;
  - b) When did the onset of the new neurologic symptoms occur?

Ms. Frogge developed twitching in her upper right quadrant as an initial neurologic symptom on May 15, 2014.

#### **Conclusion**

The parties are ordered to provide this ruling to any expert they retain. If the expert's opinion is not consistent with these findings of fact, the opinion is likely to not be persuasive. See Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (1993) (holding that the special master did not abuse his discretion in refraining from conducting a hearing when the petitioner's expert "based his opinion on facts not substantiated by the record.").

A status conference is set for **Monday**, **April 27**, **2020**, **at 2:00 P.M. Eastern Time**. Ms. Frogge should be prepared to propose the next step in this case.

IT IS SO ORDERED.

s/Christian J. Moran Christian J. Moran Special Master